

REMARKS

Favorable reconsideration of the present application in view of the above amendments and following remarks is respectfully requested. Claims 1, 5-9, 16-22 and 24-26 are pending. As set forth above, Applicants have hereby amended claims 1 and 26 to more clearly define the subject matter encompassed by the Applicants' invention. Support for amended claim 1 may be found in the application as originally filed, in part, at page 4, lines 12-14. Support for amended claim 26 may be found in the application as originally filed, in part, at page 3, lines 24-27 and at page 12, lines 2-4. No new matter has been added. Therefore claims 1, 5-9, 16-22 and 24-26 remain pending.

As an initial matter, Applicants wish to thank the Examiner for noting the change in claim 17 that was not in compliance with 37 C.F.R. §1.121(c)(2). Applicants respectfully submit that this was an inadvertent formatting error that led to the change of the charge sign "+2" from a superscript to regular case. To avoid any further confusion, and since the scope and meaning of the claims are unchanged, Applicants will not amend the charge sign "+2" of claim 17 back to superscript. In addition, Applicants have hereby amended claim 1 to make clear that the claim is intended to encompass derivatives of each of the recited specific lipopeptide antibiotics.

REJECTION UNDER 35 U.S.C. §112, SECOND PARAGRAPH (INDEFINITENESS)

In the Office Action dated April 10, 2006, claim 26 was rejected under 35 U.S.C. §112, second paragraph, as allegedly indefinite. In particular, it is alleged that it is unclear what is to be used to extract the lipopeptide from the aqueous solution – an organic solvent or an aqueous base solution.

Applicants respectfully submit that this ground of rejection has been rendered moot because claim 26 has been amended to clarify that the organic extract of the lipopeptide antibiotic from claim 1 is extracted with an aqueous base solution. Accordingly, Applicants respectfully submit that claim 26 complies with the definiteness requirements of 35 U.S.C. §112, second paragraph, and, therefore, request that this rejection be withdrawn.

REJECTION UNDER 35 U.S.C. §102(e)

In the Office Action, claims 1, 5-8, 16-22, and 24 were rejected under 35 U.S.C. §102(e) as anticipated by Borders *et al.* (U.S. Patent No. 6,511,962; hereinafter the “’962 patent”). In particular, it is asserted that the claim term “derivative” is not defined so as to require any degree of similarity between the derivative and the specific lipopeptide antibiotics recited in the claims. The Examiner further alleges that the claim term “derivative” is understood in the art to have a very broad definition, as provided in U.S. Patent Application Publication No. 2005/0288222 and U.S. Patent Nos. 6,624,289 and 6,538,028. Accordingly, it is alleged that “derivatives” of the specific lipopeptide antibiotics recited in the claims will read on laspartomycin as disclosed in the ‘962 patent. Finally, it is alleged that Examples 6 and 7 (methods of isolating laspartomycin) the ‘962 patent anticipate the claimed invention.

Applicants respectfully traverse this ground of rejection and submit that the ‘962 patent fails to meet every limitation of the instant claims and, therefore, fails to anticipate the claimed invention. As recited in the claims, the instant invention is directed, in pertinent part, to methods for purifying derivative lipopeptide antibiotics, such as derivatives of any of the following lipopeptide antibiotics: zaomycin, crystallomycin, amphomycin, aspartocin, glumamycin, daptomycin, antibiotic A1437, antibiotic A-21978C, antibiotic A-54145 or tsushimycin. The word “derivative” has a plain and ordinary meaning to those of ordinary skill in the art. For example, Stedman’s Medical Dictionary (27th Edition, 2000, at page 479) defines derivative as “a chemical compound that may be produced from another compound of similar structure in one or more steps, as in replacement of H by an alkyl, acyl, or amino group” (copy enclosed). In other words, a “derivative” is a modified version of a chemical compound that is structurally similar to a parent compound and is derived (actually or theoretically) from that parent compound (*see, e.g.*, specification at page 4, lines 12-16, in which reference is made to documents that disclose exemplary derivatives).

Laspartomycin is not structurally similar to any of the lipopeptide antibiotics listed in claim 1 (*i.e.*, zaomycin, crystallomycin, amphomycin, aspartocin, glumamycin, daptomycin, antibiotic A1437, antibiotic A-21978C, antibiotic A-54145 or tsushimycin) because, although it has

a cyclic core peptide, the amino acid sequence of the cyclic core peptide differs from those being claimed. It is well established that patent claims are to be given their broadest reasonable interpretation during examination – that is, the broadest reasonable meaning of the words in their ordinary usage as they would be understood by one of ordinary skill in the art and consistent with the specification (*see, e.g., In re American Academy of Science Tech Center*, 367 F.3d 1359, 70 USPQ2d 1827 (Fed. Cir. 2004) and *In re Morris*, 127 F.3d 1048, 1054-55, 44 USPQ2d 1023, 1027-28 (Fed. Cir. 1997)). Thus, construing “derivative of compound A” (*e.g.*, amphomycin) to include a completely different and structurally unrelated “compound B” (*e.g.*, laspartomycin) is not a reasonable interpretation of the plain meaning of “derivative” as would be understood by one of ordinary skill in the art. Moreover, it is well known in the art that lipopeptide antibiotics are biologically produced (by microorganisms; *see, e.g.*, specification at page 2, lines 3-22), but there are no known methods for changing the amino acid sequence of the core cyclic peptide of these biologically produced lipopeptide antibiotics (nor has the Examiner provided any evidence of known methods for making, or compounds with, such modifications). Therefore, the derivative lipopeptide antibiotics of the claimed invention do not (and cannot) read on laspartomycin.

Finally, U.S. Patent Application Publication No. 2005/0288222 ('222 publication) and U.S. Patent Nos. 6,624,289 ('289 patent) and 6,538,028 ('028 patent) were cited for the proposition that "derivative" is allegedly understood to have a very broad meaning in the art. Applicants submit that these references are inappropriate for determining how a claim term is to be interpreted because an inventor is entitled to be his or her own lexicographer and may rebut the presumption that claim terms are to be given their ordinary and customary meaning by clearly setting forth a definition of the term that is different from its ordinary and customary meaning(s). See *International Rectifier Corp. v. IXYS Corp.*, 361 F.3d 1363, 1368, 70 USPQ2d 1209, 1214 (Fed. Cir. 2004). Indeed, the inventors of the '222 publication and the '289 patent are giving "derivative" a meaning beyond what is ordinary and customary by, for example, including mimetics. A mimetic is generally unrelated to a parent compound (*i.e.*, it may have similar function with an entirely different structure), while a derivative is generally structurally related to a parent compound. The definition of "derivative" found in '028 patent is consistent with the plain and ordinary meaning:

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modifying a compound to derive a new compound with a similar structure. Therefore, the '028 patent supports the position that the derivative lipopeptide antibiotics of the claimed invention do not read on laspartomycin.

Accordingly, Applicants respectfully submit that the instant claims distinguish patentably over the '962 patent and, therefore, satisfy the requirements of 35 U.S.C. §102(e). Applicants request that this rejection be withdrawn.

REJECTION UNDER 35 U.S.C. §103(a)

In the Office Action, claim 9 was rejected under 35 U.S.C. §103(a) as obvious over the '962 patent. In particular, it is asserted that common ownership between the instant application and the '962 patent has not been shown.

Applicants respectfully traverse this ground of rejection and again submit that this rejection is inappropriate. Applicants agree with the Examiner that Applicants previously made a showing of common ownership between the parent application 09/948,374 and the '962 patent. Applicants note that the '962 patent was a continuation-in-part of the parent '374 application and that the instant application is a continuation of the '962 patent. Therefore, the claimed invention was made, at the latest, at the time the '962 patent was filed. As provided by 35 U.S.C. §103(c)(1), "[s]ubject matter developed by another person, which qualifies as prior art only under one or more of subsections (e), (f), and (g) of section 102...shall not preclude patentability...where the subject matter and the claimed invention were, at the time the claimed invention was made, owned by the same person..." (emphasis added). Consequently, Applicants submit that it was proper to show common ownership between the parent '374 application and the '962 patent. Furthermore, as previously made of record, the '374 application, the '962 patent and the instant application were all acquired by Micrologix Biotech Inc. (now Migenix Inc.).

Accordingly, common ownership at the time of invention has been properly established and, therefore, U.S. Patent No. 6,511,962 is not available as prior art under 35 U.S.C. §103(a) as provided by 35 U.S.C. §103(c)(1). Hence, Applicants request that this rejection be withdrawn.

Respectfully submitted,

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